

Good morning. It is a pleasure to be here this morning to address the Committee on this very important topic. My name is Dr. Jim Young, and I am the President of Research and Development at MedImmune, Inc., a biotechnology company headquartered in Gaithersburg, MD. As you may know, MedImmune is new to the influenza vaccine business having introduced a new type of flu vaccine this past year called FluMist, approved by the FDA for use in healthy individuals 5 to 49 years old. Unlike the other flu vaccines which are injected into the muscle, this vaccine is simply sprayed into the nose to protect against influenza.

MedImmune currently has the manufacturing capacity to produce 20 million doses of FluMist. This year, however, we produced only 2 million doses of bulk vaccine and before this week's events, had planned on filling and finishing only 1.1 million of those doses, which we did. That finished material, I am pleased to report, was released for distribution by the FDA yesterday.

I'm sure you're sitting there thinking, "With a capacity to produce 20

million doses of this innovative vaccine, why did we only fill only 1.1 million doses?" Quite simply, because the product

- 1) was approved with a very narrow indication by the FDA,
- 2) has been faced with significant confusion and even misinformation propagated in the marketplace,
- 3) has not had strong support from the recommending authorities, and
- 4) was launched into a climate of overwhelming complacency and with a lack of awareness on the part of the public as to the severe illness and death that is associated with influenza.

It is these factors that account for an insufficient demand to justify increased production of FluMist.

Nearly eight months ago, I sat before this committee, testifying that close to 4 million of the 5 million FluMist doses manufactured last season would be destroyed at the end of the 2003-2004 influenza season, a season in which there was a vaccine shortage and 152 children died from flu. Thirty nine of those children actually were eligible to receive FluMist and could have received the vaccine, but didn't. The fact of the matter is that there were 4 million lost

vaccination opportunities with product we had available that went unused.

Consequently, as a result of last season's experience and based upon FluMist's existing license for the restricted population of healthy individuals age 5 to 49 years, MedImmune planned very limited production this season, somewhere between one and two million doses. This was a substantial about-face from our original intent when we decided to enter the influenza vaccine business nearly three years ago with the desire to increase the number of influenza manufacturers in the U.S. and work to fulfill the stated goals of public health officials to expand the number of U.S. citizens receiving influenza vaccination.

However, in response to the vaccine shortage announced this week, we have committed to filling the remaining bulk material we have in inventory starting today and expect to produce up to 1 million **additional** doses of FluMist for distribution. Under normal circumstances, getting these additional lots of FluMist approved and released by the FDA would likely take well into December. However,

we are in communication with the FDA and are hopeful that with their assistance, the timing of this release can be expedited. As they did during the flu crisis last season, the FDA has also indicated that it may be willing to consider waiving other logistical and distribution requirements, including the need for a freezebox to store vaccine in frost-free freezers, in order to broaden the distribution of these additional doses. None of these expedited procedures will, of course, pose any added risk to the consumer or to the quality of the product. By producing up to 2 million doses for the healthy population between 5 and 49, we are freeing up 2 million doses of the injectible vaccine for use in the highest risk population, which could potentially save hundreds of lives.

After our initial "very disappointing" and sobering experience as a flu vaccine manufacturer, we spent several months earlier this year evaluating whether we should remain in the influenza vaccine business, or whether we should "cut our losses and get out " after dealing with the costly and overwhelmingly difficult regulatory landscape to bring this new and effective vaccine to market. Our partner with FluMist last year, Wyeth, a former manufacturer of the

inactivated flu vaccine, also went through this same internal debate.

In April, Wyeth opted to exit while MedImmune decided to stay in the business.

MedImmune's decision to stay in the flu business was based on our continuing belief that influenza is an extremely important disease, AND that FluMist is an important new advance in prevention, warranting our investment to become a meaningful contributor to vaccine production in this country. Since taking over complete control of the future of FluMist, we have cut the price of the product from \$46 per dose last year to a price as low as \$16 per dose this year for the private market and negotiated even lower prices for government purchases. We are currently working with the CDC, VA and DoD, providing them the option to purchase a significant proportion of the additional product we are now working to deliver to the marketplace.

While we are all here today because of an immediate and serious vaccine shortage, I want to emphasize that the problem is much

larger, and transcends well beyond this season. As Speaker of the House, Dennis Hastert stated on Wednesday, "There are only a handful of vaccine manufacturers left in the world. We know that our current production capabilities would not be able to handle a massive surge for vaccine products caused by a flu crisis. We need to take steps to address this situation before it becomes an even bigger problem."

Bigger? How much bigger does this problem need to become. How many more hearings, analyses, consultants, discussions, and testimonies must there be before any action is taken. Already, King Pharmaceuticals, Wyeth, Parke-Davis, and Merck have pulled out of the influenza vaccine business over the past few years.

So why are they exiting? Two reasons.

First, to participate in the influenza vaccine business requires enormous investment in clinical development, facilities and regulatory requirements and, currently, the return on the investment is abysmal given the low price received for the vaccine. On our part, MedImmune has already invested \$1 billion to bring FluMist to the

market with what is a very narrow label and expects to invest \$200 million more in an attempt to expand the indication to a broader U.S. population.

Second, the demand for influenza vaccine is inconsistent, such that when manufactures increase capacity in anticipation of broader demand, interest often wanes and un-used product is wasted.

Demand is strongly influenced by policies set by federal health authorities. Current influenza vaccine recommendations primarily target high-risk individuals. However, the burden of influenza illness is significant in healthy persons who fall outside these targeted age groups as well, and in otherwise healthy unvaccinated school-age children who serve as vectors for transmission of influenza to their families and to high-risk individuals with whom they have contact.

The vast majority of stakeholders in influenza prevention are reaching the same conclusion: that the recommended population for influenza vaccination must be greatly expanded, a movement that we all endorse. A universal recommendation that all Americans receive annual flu vaccine will drive the demand for routine annual

vaccination and the development of sufficient infrastructure to deliver the vaccine, which will in turn, provide the impetus on the part of vaccine manufacturers to increase their production. This will also insure the capacity needed to produce even larger quantities of vaccine in the event of the emergence of a new pandemic strain. Ironically, it is a situation like the one we're now faced with, where we are telling healthy individuals NOT to get vaccinated, which runs counter to the message public health authorities need to send to EXPAND demand. And unfortunately, history tells us that it will take several years before many healthy individuals again seek vaccination for flu.

So what is it that MedImmune would specifically recommend the federal government do?

First, we believe that regulatory authorities should look again at the available scientific and clinical data pertaining to FluMist, and reconsider a broader role FluMist could potentially play within the context of public health given the benefits that have been

demonstrated in clinical studies of this vaccine.

Second, the government needs to find ways to incentivise companies to build manufacturing facilities in the U.S. There is an increasing trend for U.S.-based companies to build manufacturing plants offshore in order to gain access to a well trained pool of potential workers as well as significant tax advantages. With this trend, comes the increased risk of the type of event we are currently experiencing, companies will face regulatory decisions that may prevent product from entering the U.S., or worse yet, in the event of a catastrophic event or the emergence of a new pandemic strain, the host country may embargo vaccine for use within its own borders.

Third, logistical and accounting issues need to be sorted out so that the federal government can stockpile either additional product or even bulk vaccine, a relatively inexpensive step in the manufacturing process. Bulk material could be stored for up to 2 years or until a new influenza strain is introduced, and could be filled at a defined schedule as needed.

Finally, the federal government should provide incentives for manufacturers to develop innovative production methods that could expand capacity, make potential new vaccine strains available to manufacturers sooner and eliminate the need for the FDA release of flu vaccine lots. All of these would result in earlier and greater product availability.

In conclusion, I'd like to reiterate that MedImmune currently has the manufacturing capacity to produce 20 million doses of influenza vaccine and with the addition of our new \$75 Million state-of the-art manufacturing facility currently being validated and modest changes in the works to our current fill/finish facility, we will soon be able to produce 40 to 50 million doses. However, in order to make production at these levels a viable option, we need the federal government to help create sufficient support and demand, to reduce regulatory hurdles and to place a far higher value upon influenza vaccination for all Americans.

Thank you again for this opportunity to speak to you today.